

REMARKS/ARGUEMENT

I. Status of the Claims

Claims 8 – 11 are pending in the subject application.

Claim 8 is allowed.

Claims 9 – 11 are rejected based on new references cited by the Examiner.

In the current response:

Applicants will sequentially address the new rejections by the Examiner.

II. The 35 U.S.C. §103 (a) Claim Rejection (Claim 9)

Claim 9 is rejected under 35 U.S.C. §103 (a) as being unpatentable over Iwai et al. (US 6,387,417 referred as Iwai et al.). Specifically Examiner states the following reasons for the rejection:

- 1) "... Examiner considers the intensifying of SOD activity and reducing of MDA level an inherent effect or mechanism by which the bamboo extract exerts its ***infection*** treatment.".
- 2) "It would have been obvious to one having ordinary skill in the art ...in view of Iwai et al., to treat ***infections*** by administering or applying Iwai et al.'s bamboo extract to an animal or infected site such as skin...".
- 3) "...Ohmoto et al.'s composition is obtained from the ***same*** source as applicant's composition and comprises the same component or substance..." (referred as Ohmoto et al., cited in previous office actions) .

The previously amended Claim 9 is directed to a method "...for intensifying SOD activity or reducing MDA level of the skin or hair in a subject...".

The method is directed to anti senescence (process of aging) by intensifying SOD activity or reducing MDA level. Applicants state in the current application that "These results showed...notable activity of scavenging active oxygen radicals... in the application of bio-antioxidants. (Example 3)", and in Example 6: "6.2.1 Effect of

retarding skin senescence: MDA level of skin cells was significantly reduced...while SOD activity was significantly intensified...”.

In contrast, Iwai et al. teaches a compound “hinokitiol” for anti bacterial applications. Iwai et al. teaches that some extracts from plants including low striped bamboo “...serve to enhance the **anti bacterial activity**... of hinokitiol...”.

Ohmoto et al. is silent about the method or application of the Triterpenoids. Ohmoto et al. teaches Triterpenoid compounds isolated from Arundinarieae genus of Gramineae family. In comparison, Applicants’ compounds are isolated from Phyllostachys, Bambusa or Dendrocalamus genus of Gramineae family, from which the compounds may not necessarily be the same since they are isolated from different genera.

Ohmoto et al. is silent about the method or application of Triterpenoid compounds to anti senescence.

Apparently, anti senescence treatment through applying antioxidant is in different category of medical knowledge from the knowledge of antibacterial treatment (antibacterial infection). One skilled in the art of anti senescence treatment can not apply his/her knowledge to antibacterial treatment, and vice versa.

Examiner fails to establish the connection between the two knowledge categories, to indicate why an enhancer (an extract used as an auxiliary) in antibacterial treatment can be specifically employed in anti senescence treatment.

Since there are no facts have been established on record, it is presumed that the examiner is relying on personal knowledge to make the rejection. Pursuant to MPEP 707 and 377 CFR 1.104(d)(2), the examiner is respectfully requested to provide an affidavit stating and supporting the allegations that it is well known in the art that antibacterial treatment have the same or similar effect as anti senescence treatment and the art of bacterial infection treatment and the art of anti senescence treatment can be used interchangeably.

The standard for making an obviousness rejection is currently set forth in MPEP 706.02(j):

To establish a prima facie case of obviousness, ***three basic criteria*** must be met. ***First***, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. ***Second***, there must be a reasonable expectation of success. ***Finally***, the prior art reference (or references when combined) ***must teach or suggest all the claim limitations***. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (emphasis added)

See also, KSR International Co. v. Teleflex Inc., No. 04-1350, 550 U.S. (2007)

Since motivation, reasonable expectation of success and claim limitation are all missing from the cited references, either by themselves or combined together, in term of applying the antibacterial treatment to anti senescence treatment, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

III. The 35 U.S.C. §103 (a) Claim Rejections (Claims 10 and 11)

Claims 10 and 11 are rejected under 35 U.S.C. §103 (a), as being unpatentable over the reference of Kobayashi et al. (Bull Fac Agr., Meiji Univ. (115): 39 - 44,1998) (referred as Kobayashi).

Examiner states: “Kobayashi et al. disclose that an extract of bamboo leaves suppress (inhibit) markedly the development and growth of spontaneous mammary tumors of SHN mice.”.

Examiner asserts: “...Kobayashi et al. do not disclose the components and their percentages in said bamboo extract. However, Kobayashi et al.’s composition is obtained from the same source as applicant’s composition and **should comprise the same components or substance...should have the same total percentages...**”.

Applicants reviewed the cited reference and respectfully submit that the above statements are incorrect and the reference is misinterpreted. Applicants traverse these rejections in the following paragraphs.

Kobayashi is silent about the substance which has anti tumor effect. Sasa Health is a trade name of an extract of bamboo grass leaves with undefined composition, to “...enhance intrathymic differentiation.”. According to Kobayashi, the extract “...decreased the proportion of immature (CD4+CD8+) thymocytes and increased the percentage of mature cells...(CD4+CD8-) ... (CD4-CD8+) (Kobayashi, Summary) Kobayashi’s method does not reveal any data that Sasa Health is able to inhibit any tumor cells.

In addition, Kobayashi is silent about the anti tumor mechanism as disclosed by the present invention. Please note that the thymus is **a normal organ** in the chest of many kinds of animals (not a tumor), and thymocytes are **normal cells** (not tumor cells). Apparently Kobayashi teaches an indirect anti tumor therapy, in which the mature thymocytes are enhanced, and then the thymocytes may suppress the tumor cells, as Kobayashi speculates.

Kobayashi speculates that the thymic enhancing effect from Sasa Health will in turn “...suppress (inhibit) markedly the development and growth of spontaneous mammary tumors of SHN mice.”, therefore Sasa Health has “anti tumor potential” (Kobayashi, Summary and line 1-2, page 40). However, Kobayashi is silent how the thymic enhancing effect of Sasa Health will turn to anti tumor effect, the mechanism of the first effect on the second effect is not stated.

In the present invention, Claim 10 is directed to a method “...of inhibiting growth of cancer cells or tumor cells, comprising treating the cancer cells or tumor cells a therapeutically effective amount of total triterpenoid saponins extracted from bamboo ...”. In the claimed method chemically defined compounds with determined dosages treat the cancer cells or tumor cells directly. Applicants disclose detailed method of treating cancer and tumor in controlled experiments (both positive controlled and negative controlled) with defined compounds, compositions, dosages and demonstrated direct inhibition results on cancers or tumors (Please see Example 5 of the specification).

Kobayashi does not teach all the limitation of the claimed subject matter, since indirect inhibition of tumor growth differs from direct inhibition of tumors in terms of mechanism, composition, dosage and administration. Nor Kobayashi suggests the

motivation why an indirect anti tumor method can be turned into a direct anti tumor method. Therefore a person skilled in the art will not succeed to apply Kobayashi's method to the present invention.

The chemical composition of Kobayashi's Sasa Health is different from that claimed by the Applicants, since Sasa Health is "an alkaline hydrolytic extract of bamboo grass leaves". In contrast, the present invention discloses, among various embodiments, a unique method using supercritical condition to extract high concentration of the total triterpenoid sapogenins to overcome deficiency of chemical extraction methods. As described by the Specification of this Application:

"....., the extraction method of chemical solvents has many defects such as long operation, great solvent consumption and bad operational environment. Furthermore, the extract obtained by organic solvent extraction has unstable product quality, high contents of heavy metal and pesticide residue and low extraction yield...." (Paragraph [0019])

Kobayashi is silent about "a therapeutically effective amount of total triterpenoid sapogenins extracted from bamboo, wherein total triterpenoid sapogenins is 10-90% as determined by vanillic aldehyde and perchloric acid colorimetry using friedelin as a standard, said total triterpenoid sapogenins comprising 5-35% friedelin and 1-10% lupenone as determined by GC-MS", as cited in claim 10 of the present invention. Since there are no facts have been made on record that 1) Kobayashi's undefined Sasa Health "**comprise the same components or substance**" and "**have the same total percentages**" as that cited in claim 10 of the present invention. 2) **why an indirect anti tumor therapy can be changed to treat tumor directly**, it is presumed that the examiner is relying on personal knowledge to make the rejection. Pursuant to MPEP 707 and 377 CFR 1.104(d)(2), the examiner is respectfully requested to provide an affidavit stating and supporting the allegations that 1) it is well known in the art that any substance extracted from bamboo grass has a therapeutically effective amount of total triterpenoid sapogenins, wherein the total triterpenoid sapogenins is 10-90% as determined by vanillic aldehyde and perchloric acid colorimetry using friedelin as a standard, said total triterpenoid sapogenins comprising 5-35% friedelin and 1-10%

lupenone as determined by GC-MS. 2) an indirect anti tumor therapy can be changed to treat tumor directly.

Motivation coming from the applicant's own disclosure is not sufficient to establish a *prima facie* case of obviousness under 35 USC §103. Nor is it sufficient that those of ordinary skill in the art had the capability to combine and modify the referenced method or understand the advantage of the combination and modification.

Based on the forgoing discussions, it is respectfully contended that the cited reference (Kobayashi) does not teach or suggest all of the limitations in claim 10. Reconsideration and withdrawal of the rejection of claim 4 is respectfully requested.

Claim 11 is dependent on Claim 10, therefore are also patentably distinct over the reference of Kobayashi for at least the same reasons as those set forth with respect to claim 10. Reconsideration and withdrawal of the rejection of claim 11 is respectfully requested.

IV. Allowable Subject Matter

The Applicants thank the Examiner for holding that Claims 8 to be unobvious over the prior art of record and that Claims 8 is allowed.

V. Conclusion

The applicants respectfully request reconsideration of the claims in view of the remarks made herein. A notice of allowance is earnestly solicited.

In the event that any fee is deemed due for this Response, the commissioner is hereby authorized to charge any additional fee or to credit any overpayment in connection with this Remark to Deposit Account No. 502869.

Should the Examiner believe that further discussion of any remaining issue would advance the prosecution, he or she is invited to contact the undersigned at the telephone number listed below.

Respectfully Submitted,



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